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BACKGROUND OF THE INVENTION

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3 This invention relates generally to the
4 alignment and fixation of bone segments as required for
5 appropriate bone healing, for example after fracture or
6 surgical intervention, and specifically to a device,
7 and the tools needed to install the said device, for
8 the alignment and fixation of cranial bone fragments.

9 In cases of bone fragmentation where bone
10 fixation is desired, the appropriate alignment of the
11 bone is also a desired result. This is especially true
12 in the cranium, where bone fragmentation can occur as a
13 result of trauma, congenital deformity, or of surgical
14 intervention. In the field of neurosurgery, cranial
15 bone fragments are frequently cut and removed to create
16 defects to allow for access into the cranial cavity and
17 the brain.

18 The bony cranium is generally regarded to
19 have two surfaces: the outer surface which is
20 characterized by the outer cortex of the bone and is
21 adjacent to the scalp and soft tissue; and the inner
22 surface which is characterized by the inner cortex of
23 the bone and which is adjacent to the cranial cavity
24 and the brain. Between the inner cortex and the outer
25 cortex, which are dense layers of bone, lies the diploe

1 which generally consists of soft bone and bone marrow.
2 When a bone fragment is created, a cut between the bone
3 fragment (the primary bone zone) and the remainder of
4 the cranium (the secondary bone zone) is present.

5 Several methods of alignment and fixation of
6 primary and secondary bone zones are known.

7 Traditional techniques involve the use of several
8 pieces of filament, such as wire, that are tied after
9 being threaded through holes drilled obliquely through
10 the outer cortex to the cut surface of both bone zones.
11 Precise alignment of the two zones can be difficult and
12 the technique can be cumbersome.

13 Commonly, the zones of bone can be aligned
14 and fixated with a system of plates and screws (U.S.
15 Patents: 5,372,598; 5,413,577; and 5,578,036). A
16 plate made of metal or other substance can be fixated
17 to the outer cortex of the primary bone zone with
18 screws whose penetration of the bone can be limited to
19 the outer cortex. With three or more plates attached
20 to the primary bone in such a way that the plates
21 protrude beyond the edges of the primary bone zone, the
22 primary bone zone can be introduced into a defect and
23 aligned to the outer cortex of the secondary bone zone
24 without danger of the primary bone zone falling too
25 deeply into the defect in the secondary bone zone and
26 exerting pressure on the underlying tissue such as the

1 brain. Fixation can then be achieved by employing
2 additional screws fixating the plates to the outer
3 cortex of the secondary bone zone. Plates and screws
4 systems allow for the alignment and fixation of the
5 zones, while preventing the primary bone zone from
6 falling below the level of the secondary bone zone
7 without actually introducing a component of the device
8 below the secondary bone zone. A plate with a spring
9 clip extension has been described (U.S. Patent
10 5,916,217). Plate and screw systems can be expensive
11 and time consuming to use.

12 Devices that align the two bone zones by way
13 of compressing them between the two disks positioned
14 along the inner and outer cortex have been described.
15 (Foreign Patents: DE 19603887C2, DE 19634699C1,
16 DE 29812988U1, EP 0787466A1.) A pin connects the two
17 disks aligning and securing two bone zones. These
18 devices introduce foreign material that is left below
19 the inner cortex, and they do not protect the
20 underlying tissue from compression during the
21 installation procedure.

22 Devices that fixate bone zones using friction
23 forces created by a cam without a component that
24 extends below the inner cortex are known and described
25 (Patent DE 19634697C1). These devices also do not

1 protect the brain from compression during the
2 installation procedure.

3 Intramedullary pins are well known in the
4 orthopedic fields for alignment of long bones. Such
5 pins have also been described for cranial fixation
6 (U.S. Patent 5,501,685); however, the bone zones can
7 not be aligned in three dimensions with this technique.

8 There is a need for an alignment and fixation
9 device that is simple and rapid to use, versatile, and
10 ultimately cost effective.

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12 **OBJECTS OF THE INVENTION**

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14 The object of the invention is to provide a
15 device and instruments for its use that aligns the one
16 cortex of a primary zone with one cortex of a secondary
17 bone zone without extending to the opposing cortex, and
18 which fixates the bone zones to each other. When used
19 in the field of neurosurgery, the device is applied to
20 the primary bone zone and it aligns the outer cortex of
21 the primary bone zone with the outer cortex of the
22 secondary bone zone; it prevents the primary bone zone
23 from entering the cranial cavity; and it provides
24 fixation of the two bone zones. The alignment feature
25 can be used independently from the fixation feature.
26 An example of the use of the alignment feature is in

1 the replacement of a cranial bone fragment which will
2 be held in place by the tissue forces of the scalp,
3 which allows for the bone fragment to be elevated away
4 from the cranial cavity in cases where brain swelling
5 occurs. Fixation can also be applied to attach the
6 alignment device to the bone, using elements alone or
7 in combination such as filaments, screws, rivets, pins,
8 clips, cams, friction or adhesives. The alignment
9 aspect of the invention can also be applied to
10 situations where it is desired to offset the alignment
11 of the bone fragment to the adjacent bone such as where
12 the object is to create a more prominent chin by
13 cutting the bone of the chin and advancing the bone
14 fragment.

15 The fixation feature of the invention is
16 likewise independent from the alignment feature. The
17 fixation feature of the device relies on the principle
18 that the device is fixated to the primary bone zone and
19 the fixation feature grips the secondary bone zone by
20 means of spring loaded tab or hook elements engaging
21 the soft areas of the medullary space, irregularities
22 along the cut surface, or a slot cut into the cut
23 surface of the secondary bone zone.

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SUMMARY OF THE INVENTION

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3 The invention provides an improved clip
4 meeting the above need or needs.

5 As will be seen the preferred clip is
6 configured to interconnect primary and secondary bone
7 zones having edges spaced apart by a gap, the clip
8 comprising

18 As will be seen, the barb may be located
19 at an edge of the second tab; and the barb may have a
20 tip offset from a plane defined by the second tab. In
21 this regard, the second tab preferably has a
22 multiplicity of barbs oriented to engage the primary
23 bone zone to resist displacement of the second tab in
24 the direction toward the secondary bone zone. Such
25 barbs may typically extend in at least one row, in said

1 direction; and they preferably extend in two parallel
2 generally longitudinal rows. An anchor element is
3 typically provided on the first tab for use in
4 anchoring the first tab to the secondary bone zone.

5 Another object includes provision of a
6 retainer operatively connected with at least one of the
7 first and second tabs and projecting for retention to
8 at least one of the bone zones at a retention level
9 spaced from levels defined by those tabs. That
10 retainer typically comprises a third tab spaced from
11 the first and second tabs. Also, the third tab
12 preferably has a multiplicity of barbs oriented to
13 engage the primary bone zone to resist displacement of
14 the third tab in the direction toward the secondary
15 bone zone.

16 A yet further object includes provision of a
17 projection associated with at least one of the tabs,
18 and configured to engage the secondary bone zone at the
19 edge thereof, and in spaced relation to the tabs.
20 That projection typically has a sharp terminal to
21 enable penetration of diploe; and it extends at an
22 acute angle relative to a plane defined by said one
23 tab. Further, a spring arm typically connects the
24 projection to the at least one tab, so that the
25 projection extends downwardly into a gap formed by
26 edges of the primary and secondary bone zones.

1 These and other objects and advantages of the
2 invention, as well as the details of an illustrative
3 embodiment, will be more fully understood from the
4 following specification and drawings, in which:

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6 **DRAWING DESCRIPTION**

7 Figs. 1 and 2 are perspective views of a
8 preferred form of clip embodying features of the
9 invention;

11 Fig. 3 is a side elevational view of the Fig.
12 1 clip;

13 Fig. 4 is another side elevational view of
14 the Fig. 1 clip;

15 Fig. 5 is a top plan view taken on lines 5-5
16 of Fig. 4;

17 Fig. 6 is a first elevational view taken on
18 lines 6-6 of Fig. 4;

19 Fig. 7 is a top plan view of a blank from
20 which a structural component part of the clip is to be
21 formed; and

22 Fig. 8 is a top plan view of a blank from
23 which a spring component part of the clip is to be
24 formed.

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DETAILED DESCRIPTION

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3 In Figs. 1-5, the illustrated clip 10 is
4 configured to interconnect primary and secondary bone
5 zones 11 and 12, having opposed and spaced apart edges
6 11c and 12c. A cut or gap 13 is formed between the
7 opposed edges of the primary and secondary bone zones.
8 Diploe is shown at 15 between the top and bottom
9 surfaces 11a and 11b of zone 11; and at 16 between the
10 top and bottom surfaces 12a and 12b of zone 12. As
11 also seen in Fig. 1, primary bone zone 11 may be
12 defined by bone flap 17; and secondary bone zone 12 may
13 be defined by skull 18 and its zone extents at 12
14 opposing zone 11. In the adult, cranial bone or skull
15 averages 7mm in thickness, but varies between 3 and 12
16 mm.

17 The clip 10, which is preferably metallic
18 includes the following

- 19 a) a first tab 20 to extend proximate and
20 on a surface 12a of the secondary bone zone 12,
- 21 b) a second tab 30 associated with the
22 first tab 20, and located to extend proximate and on a
23 surface 11a of the primary bone zone 11,
- 24 c) the second tab 30 having at least one
25 barb oriented to engage the primary bone zone 11 to

1 resist displacement of the second tab 30 in a
2 longitudinal direction 31 toward the secondary bone
3 zone 12.

4 The at least one barb is shown in the form of
5 multiple barbs 33 extending in two parallel rows 33a
6 and 33b along laterally opposite edges 34a and 34b of
7 tab 30. The barbs have sharp tips 35 that are
8 typically turned downwardly, as seen in Fig. 6, to
9 frictionally engage, and penetrate the top surface 11a
10 of the bone zone 11. Additional or alternate barbs on
11 tab 30 are shown at 36, projecting downwardly from
12 medial extent 37 of the tab, to engage surface 11a.

13 Tab 20 is attachable to the top surface 12a
14 of bone zone 12, as by means of a fastener 23, that is
15 driven downwardly through an opening 24 in tab 20.
16 Opening 24 is an example of one anchor element for use
17 in anchoring the first tab to the secondary bone zone.

18 Also provided is a retainer operatively
19 connected with at least one of said tabs and projecting
20 for retention to at least one of the bone zones at a
21 retention level spaced from levels defined by the tabs.
22 In the example, the retainer comprises a third tab 40
23 spaced from the first and second tabs 20 and 30, the
24 tab 40 extending generally parallel to the second tab
25 30, and being integral with the first tab 20. Note
26 that an upright leg or strut 41 is integral with and

1 connected to ends of the horizontal tabs 20 and 40, and
2 extends adjacent the edge 11a of the bone zone 11. The
3 third tab 40 has a multiplicity of barbs oriented to
4 engage the primary bone zone to resist displacement of
5 the third tab in said direction toward the secondary
6 bone zone. Such barbs extend in two parallel rows 42
7 and 43, which are laterally spaced, and have upwardly
8 turned sharp tips 44. The latter engage the underside
9 11b of the bone zone 11 to resist rightward
10 displacement of tab 40, toward bone zone 12. See also
11 intermediate barbs 48 and 49.

12 Also provided is a projection associated with
13 at least one of the tabs, and configured to engage the
14 secondary bone zone at the edge thereof, and in spaced
15 relation to said tabs. See for example the projection
16 50 on arm 51 integral with tab 30 at turn locus 52, the
17 arm turned or extending downwardly to project through
18 an opening 53 in first tab 20 overlying the gap 13.
19 Arm 51 acts as a spring arm, for urging projection 50
20 toward edge 12a of bone zone 12. The projection 50
21 extends intermediate two parallel sections 51a and 51b
22 of arm 51, as is seen in Fig. 8 showing a blank that
23 forms 30 and 50. The projection has a sharp, tapering
24 terminal 53 to enable penetration of diploe 16 at edge
25 12a, for anchoring arm 51 and tab 30 in position, as

1 shown. The projection extend at angle α relative to a
2 plane defined by tab 30.

3 The clip 10 accordingly is configured to have
4 two associated components, the first component
5 including tab 20, extension 41 and tab 40, defining a
6 generally Z-shape. The second component includes tab
7 30, arm 51 and projection 50 also forming a generally
8 Z-shape. Further, the two components are configured to
9 interfit at the hinge location 60 where arm 51 extends
10 downward through opening 53. Barbs on the two
11 components are adapted to engage one of the bone zones
12 to resist displacement of the two components relatively
13 toward the other bone zone, as shown. Fig. 7 shows the
14 first component in blank formed condition, prior to
15 bending at 70 and 71, into generally Z-shape.

16 Accommodation to bone zones having different
17 width gaps 13 therebetween is achieved by use of the
18 spring arm 51 carrying projection 50.

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